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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,229	03/18/2004	Stuart D. Edwards	1849.16436-DIV DIV	5629

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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05/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,229

Applicant(s)

EDWARDS ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-18-04, 5-6-04, 3-16-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species VIII (Figures 12a, 12b), Claims 1 and 8 in the reply filed on 16 March 2007 is acknowledged.
2. Claims 2-8, 10-28 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 16 March 2007.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The correct statement should read:

"I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

4. Differences between the Applicant's statement and the correct statement are underlined in the sentence above.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 1 recites the limitation "the catheter lumen" in lines 9-10, 12, 14-15. There is insufficient antecedent basis for this limitation in the claim.
7. Claim 1 is unclear because the language is claiming that the static mixer is inside the catheter (line 13) and also located at an upstream flow direction *from* the catheter lumen for mixing prior to passage through the catheter lumen (line 14-15; emphasis added). According to Applicant's claim language, Applicant is claiming that the mixer is both inside the catheter (line 13) and not inside the catheter lumen (line 14-15). This is contradictory because Examiner is assuming that the catheter lumen is located inside the catheter and the mixer cannot both be located in the catheter if its mixing fluids before they are put into the catheter lumen. The fluids must be placed into the lumen before being mixed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Illi (US Patent 5,601,603) in view of Antanavich, et al. (US Patent 5,814,022) and Cates, et al. (US Patent 6,056,768).

9. Illi'603 teaches a device for introducing a sealant at a puncture site that contains a catheter (2) having a proximal end (towards 1' in Figure 1) and a distal end (12); a fluid delivery port (6) adjacent to the catheter distal end; a fluid delivery lumen (7) in the catheter in fluid communication with the delivery port (see Figure 2 and 5); a static mixer (13) located in an upstream flow direction from the catheter lumen (in element 5; see Figure 3). The mixer is also connected (via element 5) to the catheter. Illi'603 also teaches that a two-component sealant is pushed through connector (5, column 5, lines 43-58). Illi'603 does not teach a dispenser with an actuator or an expandable member.

10. Antanavich'022 teaches an apparatus for applying a sealant to human or animal tissues that contains a dispenser (1, 8) that is located at the proximal end of the device. The dispenser contains an actuator (7, which moves plungers 6 and 9) from dispensing the the first and second fluid compositions from the dispenser and urges movement

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through the catheter lumen. It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Illi'603 with the dispenser/actuator taught by Antanavich'022 in order to dispense a two-component sealant into the introducing apparatus.

11. Cates'768 teaches puncture closure device that contains an expandable balloon (21) distal to the fluid delivery port (50) (see Figure 1). The balloon extends through the puncture site and occupies a position inside the vessel in order to create a seal on the interior end of the blood vessel, which prevents unwanted clotting inside the vessel being sealed because it keeps the sealant from entering the blood vessel while it is being dispensed (column 2, lines 24-65, also Figure 6). It would have been obvious to one skilled in the art at the time the invention was made to modify a vessel puncture closure device taught by Illi'603 with a balloon taught by Cates'768 in order to prevent the sealant from entering the blood vessel while it is being deployed causing unwanted clotting.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm+, and alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lb

A handwritten signature in black ink, appearing to read 'M J Hayes', is positioned above the printed name.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER